SIEMENS

Pressure Test

SP

Service

Shock Wave Pressure and Position Control

Test and Check Specifications

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Contents 0 - 3

Page

1 Preparation 1 - 1

Use of the PTU (Pressure Test Unit) . . . 1 - 1
Required Test Equipment . . . 1 - 1
Prerequisite: Water Filling . . . 1 - 1
General Measurement Procedure . . . 1 - 2
Testing the PTU . . . 1 - 3
Measurement with the PTU . . . 1 - 3
Evaluation of Measured Data . . . 1 - 4

2 LITHOSTAR Multiline 2 - 1

Preparation . . . 2 - 1
Attaching the Test Unit . . . 2 - 1
Adjusting the Adapter . . . 2 - 1
Shock Wave Pressure Check . . . 2 - 1
Search for Maximum Pressure . . . 2 - 1
Pressure Check . . . 2 - 2

3 LITHOSTAR C-, Standard System and Modularis 3 - 1

Preparation . . . 3 - 1
Attaching the Test Unit to the LITHOSTAR . . . 3 - 1
Attaching the Test Unit to the LITHOSTAR Modularis . . . 3 - 1
Shock Wave Pressure and Position Check . . . 3 - 2
Pressure Check for the LITHOSTAR C-System and Modularis . . . 3 - 2
Pressure Check for LITHOSTAR Standard System . . . 3 - 2
End of Test . . . 3 - 2

4 OTM 4 - 1

Attaching the Test Unit . . . 4 - 1
Adjusting the SONOLINE . . . 4 - 2
Basic Axial and Lateral Settings . . . 4 - 2
Axial Adjustment . . . 4 - 2
Sensor Positioning . . . 4 - 3
Shock Wave Pressure Check . . . 4 - 4
End of Test . . . 4 - 4
Programming the Basic Settings . . . 4 - 5
Basic Axial Setting . . . 4 - 5
Basic Lateral Setting . . . 4 - 5
SONOLINE SL 1 . . . 4 - 6
SONOLINE SI 200 / SI 250 . . . 4 - 6

5 Certificate 5 - 1

6 Changes to previous version 6 - 1

Contents

Page

Use of the PTU (**P**ressure **T**est **U**nit)

- The pressure test unit can be used to check both the shock wave pressure and the agreement or coincidence of the focal position with the aiming device of the ultrasound locating system.

Required Test Equipment

• Pressure test unit	30 95 408 J1008
• Storage oscilloscope, e.g. Fluke Scope Meter	73 92 074
• PTU adapter, Multiline	70 41 028
• PTU adapter, standard system/C system	98 17 347
• PTU adapter, OTM	98 18 006
• Coupling bellows (only for Modularis)	16 12 337
• Clip (only for Modularis)	70 56 823
• Clip (for C plus shock wave head)	70 61 013

NOTICE

The PTU is a test unit which may be used only for the described checking purposes. It is not a measuring instrument for absolute values!

Prerequisite: Water Filling

NOTICE

Before the PTU is transported at near or sub zero temperatures, the water must be removed from its sensor cupola. Before putting it back into operation (after transport), wait until the glycerine filling of the actual sensor has adapted to normal operating temperature.

- The sensor dome of the test should already be filled with distilled wateror must be filled with distilled water prior to initial operation. This water filling should be changed from time to time depending on its degree of pollution due to algae (turbidity).
- The water must be allowed to "go stale" for at least 3 days. Fresh water leads to the formation of bubbles and therefore falsifies measurement results.
- Unscrew the sensor dome.
- Fill the sensor dome with distilled water, mount the sensor onto the dome from above and screw it on tight.
- Remove (cap) screw from dome.
- Use a syringe to fill water into the dome until it no longer contains any air bubbles.
- Close the hole again by reinserting the screw.

NOTICE

If a shock wave head is replaced, it also may be filled only with "stale" water. As with the dome, fresh water falsifies measurement results here too. This is due to the high gas content of the water.

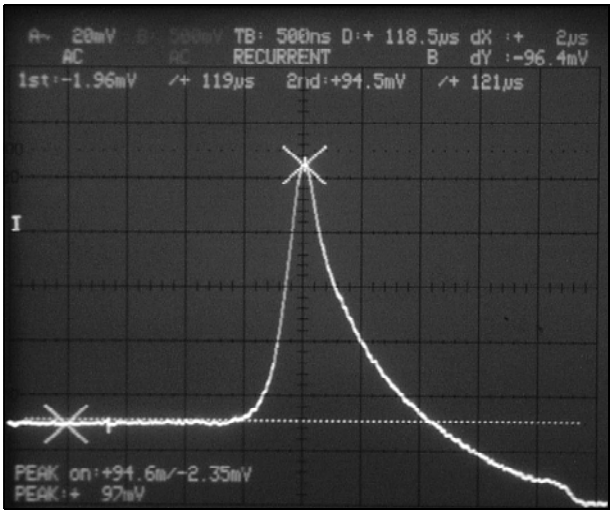


Fig. 1

General Measurement Procedure

- Due to the cumulative tolerances involved (mech. tol., temperatures, tol. in the charging power circuit, offset) the following measurement sequence must be followed.
  For absolute measuring, a scope is also required in addition to the PTU. If no comparison measurement has been done yet on a system, an absolute measurement must be performed. During this the measuring signal is evaluated with an oscilloscope and the reading on the LCD display is logged.
  If no part of the system configuration (shock wave head, charging unit, power unit, power cable) has changed, a comparison measurement via the LCD display will suffice for subsequent repeat measurements. This is done by comparing current readings with the reference values originally determined when the new shock wave head was installed.
  In case of doubt, it is generally advisable to perform the absolute measurement.
- Always perform the absolute measurement after replacing shock wave components (charging or power unit, shock wave head). This enables more exact information on parts subject to wear.
- The oscilloscope must have a sampling rate of at least 100 megasamples. The input of the scope must be terminated with **50 ohms** (not 1 megohm !).
  If no 50-ohm input is available, the sensitivity of the PTU must be recalculated accordingly (see evaluation of measuring data).
- A mean value calculation must be performed during the measurements. It is recommended that you determine the **mean value** for 5 individual measurements.
- Use of the scope's automatic functions (e.g. peak, MAX, ...) may lead to measuring errors, since these functions are usually referenced to the baseline. The latter can, however, be superimposed with an **Offset**.
  The following procedure is therefore recommended. The relevant voltage value is not the peak value, but rather the difference between the voltage in the peak and the voltage lying approx. 2 µs in front of the peak (Fig. 1).
- In the illustration (Fig. 1) the voltage difference between the cursors, which lie 2 µs apart, is 97 mV. The automatic peak function would have yielded 94.6 mV here, however the resulting difference can be much greater.

Testing the PTU

- After pressing the test button, the display reading must be between 95 and 105. Always check this value first before using the PTU.

Measurement with the PTU

NOTICE

Before beginning the measurement, trigger at least 50 shock waves at the maximum energy level. The PTU must not yet be connected at this time.

- Before attaching the PTU, **ultrasound gel** must be applied to the coupling surface between the PTU and the coupling bellows. Make sure that you apply the gel so that no air bubbles are trapped inside. Since the coupling dome of the PTU is transparent, it should be possible to check for bubbles by looking through the surface from the side. At the same time, you should also make sure that the coupling pressure is high enough. It must be possible to place the coupling bellows around the coupling dome of the PTU; if necessary, the fine pressure must be increased for the measurement of Lithostar Standard and "C" units.
- A waiting period of approx. 5 seconds must be maintained each time a shock wave is triggered in order to protect the PTU. The reason for this is cavitation in the measuring medium. In addition to its possible destructive effect, cavitation also causes falsification of measurements. With the OTM no bubble layer may be visible in the US.

NOTICE

If measurements are taken with the oscilloscope, the released energy can be more exactly determined.
This method of measurement is urgently recommended for determination of the reference value.

- Pressure measurements are generally dependent on the **water temperature**. Since the systems are generally located in rooms with controlled temperature conditions, this usually poses no problem. If, however, the heating or air conditioning system fails or measurement is performed after a prolonged therapy session, falsified measurements may result. A difference in temperature of 3 - 4°C from the last comparison measurement is not significant.
- To prevent measuring errors, a **ground cable** must always be connected directly to the PTU. An adapter plug for connecting a BNC connector to a banana socket is provided for this purpose. The black banana socket must be connected to a ground point near the shock wave head via a cable. Make sure that this connection has good contact. Failure to connect this cable properly will result in triggering and measuring errors. Furthermore, in this case the reference level for the measuring electronics is not clearly defined, thus also leading to noticeable measuring errors.
- The absolute peak is not decisive for the evaluation, but rather the voltage differences between the peak value and the value 2 µs before the peak (Fig. 1).
- The measured value should be determined by averaging at least five individual measurements.

Evaluation of Measured Data

- The calculated mean value of the measurements must be divided by the mean sensitivity of the PTU. In this case the mean value of the 3 individual sensitivities specified in the calibration certificate must be determined for the measurement via LCD display (comparison measurement) or oscilloscope (absolute measurement).
  The measured values are thus comparable even if a second PTU is used; e.g. if the original one had to be replaced because of a defect.

Example:

	Sensitivity of analog output, 50 ohms [mV/MPa]	Sensitivity of digital display [value/MPa]
	4.69	0.89
	4.99	1.01
	7.10	1.42
Mean sensitivity value	**5.59**	**1.11**

- LCD display: 100: Pressure value: 100 / 1.11 = 90.1
- Analog value: 504: Pressure value: 504 / 5.59 = 90.1

If the scope has no 50-ohm input, the sensitivity of the analog output must be doubled. In the example shown above, this would mean:

- Analog value: 1008: Pressure value: 1008 / (2*5.59) = 90.1
- Enter determined values in certificate.

Preparation

NOTICE **Before beginning the measurement, trigger at least 50 shock waves at the maximum power level. The PTU must not yet be connected at this time.**

Attaching the Test Unit

- Switch on the LITHOSTAR Multiline.
- Remove the urological insert.
- Move the shock wave head to the gel position.
- Move the shockwave head to the therapy position.
- Remove the three cover plugs from the upper casing.
- Mount adapter and fasten it with screws.
- The PTU must be filled with distilled water (see Preparation, Chapter 1).
- Clean the coupling surface of the shock wave head and the PTU with a moist cloth. Then apply ultrasound coupling gel to the surface evenly and generously. Take care to apply the coupling gel as free of bubbles as possible.
- When inserting the PTU in the adapter, make sure that no air bubbles are trapped in the gel between the coupling bellows and the dome.

Adjusting the Adapter

NOTICE **Due to the size of the focal point, the PTU must be centered.**

Shock Wave Pressure Check

Search for Maximum Pressure

- Switch on the PTU.
- Trigger a single shot at the maximum energy level, since the result is most accurate at this setting.
- Reset the PTU following each shot (observe waiting period of approx. 5 seconds).
- Use knurled screws to displace in Y direction until maximum pressure has been reached.
- Repeat this procedure in the X direction.
- Repeat the procedure again until no additional pressure increase is possible.
- For the following pressure measurement, it should be possible to exactly determine the maximum at approx. 0.2 mm (1 full turn equals 0.5 mm).

Pressure Check

- The pressure check is performed at energy level 4.5.
- Default value:
  Absolute measurement: 33.2 - 48.9 MPa
  Comparison measurement: Original value $\pm$ 10%.
- Enter values determined in certificate.

Preparation

Attaching the Test Unit to the LITHOSTAR

- Switch on the lithotriptic system.
- Insert the lithotriptic table insert.
- Select the left or right shock wave head.
- Clean the coupling surface of the shock wave head and the PTU with a moist cloth. Then apply ultrasound coupling gel to the surface evenly and generously. Take care to apply the coupling gel as free of bubbles as possible.
- Mount the adapter on the shock wave head and connect it by turning the bayonet catch clockwise.
- Move the shock wave head into its working position.
- Insert the PTU in the adapter.
- Force out any gas or air bubbles which may be trapped in the coupling area by repeatedly twisting the test unit back and forth.
- Check the PTU for wrinkle-free coupling through the adapter window; correct if necessary.

Attaching the Test Unit to the LITHOSTAR Modularis

parts for replacing the coupling bellows:

- Coupling bellows 16 12 337.
- Clip 70 56 823.
- For C plus shock wave head a new clip (Clip C plus) with the part number 70 61 013 is required to restore the original condition.

NOTICE

To ensure uniform measuring conditions, the adjusting adapter and coupling bellows must be removed from the LITHOSTAR Modularis and replaced by the coupling bellows of the C-head. If air bubbles are visible below the lens of the shock wave head, ca. 500 shock waves must be triggered at a medium energy level. Air bubbles below the lens would falsify the measured result.

- Clean the coupling surface of the shock wave head and the PTU with a moist cloth. Then apply ultrasound coupling gel to the surface evenly and generously. Take care to apply the coupling gel as free of bubbles as possible.
- Mount the adapter on the shock wave head and connect it by turning the bayonet catch clockwise.
- Insert the PTU in the adapter.
- Force out any gas or air bubbles which may be trapped in the coupling area by repeatedly twisting the test unit back and forth.
- Check the PTU for wrinkle-free coupling through the adapter window; correct if necessary.

NOTICE

One special point must be observed when measuring on the standard head via the LCD display.
In order to measure via the LCD display, the output of the PTU must be connected to the output of the measuring shunt (for current measurement) of the shock wave generator. A T-piece and a coaxial cable are required for this purpose to ensure reliable triggering.

Shock Wave Pressure and Position Check

Pressure Check for the LITHOSTAR C-System and Modularis

- The pressure check is performed at energy level 4.5.
- Default value
  Absolute measurement: 42.3 - 66.7 MPa
  Comparison measurement: Original value ± 12%
- Enter values determined in certificate.

Pressure Check for LITHOSTAR Standard System

- The pressure check must be performed at the 19 kV energy setting.
- Default value
  Absolute measurement: 42.9 - 62.5 MPa
  Comparison measurement: Original value ± 10%
- Enter values determined in the certificate.

End of Test

- Remove the PTU from the shock wave head.
- Perform pressure check on the second shock wave head if necessary.
- Reattach the blue coupling bellows to the LITHOSTAR Modularis.
- Clean the coupling surface of the shock wave head and the PTU with a moist cloth.

Attaching the Test Unit

- Switch on the lithotriptic system and/or select the overtable module.
- Position the shock wave head:

  - in the working range
  - outside of the table
  - in the horiz. position
  - at arm height

- The internal US applicator (probe) is fully retracted.
- Unscrew the holding knob from the shock wave head and insert the two special knurled screws there and on the opposite side of the head.
- Clean the coupling surface of the shock wave head with a moist cloth.
- Use the handles of the adapter to turn the adjusting ring for the coupling pressure counter-clockwise.
- Clean the coupling surface of the PTU with a moist cloth.
- Finally, apply ultrasound coupling gel evenly and generously to the coupling surface.
- Insert PTU adapter in shock wave head on knurled screws with the triangular marks pointing upward.
- Use handles to turn adapter clockwise and tighten locking screw securely.

NOTICE

The coupling pressure must be developed via the PTU adapter to zero in the shock wave head; the shock wave run-in must not be performed with the PTU attached.

- Carefully insert the PTU in the coupling device.
- Use the handles to turn the adjusting ring until the required coupling pressure has been reached.

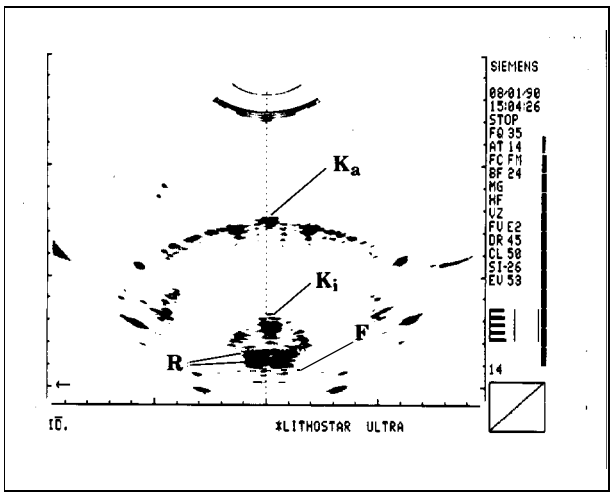


Fig. 1

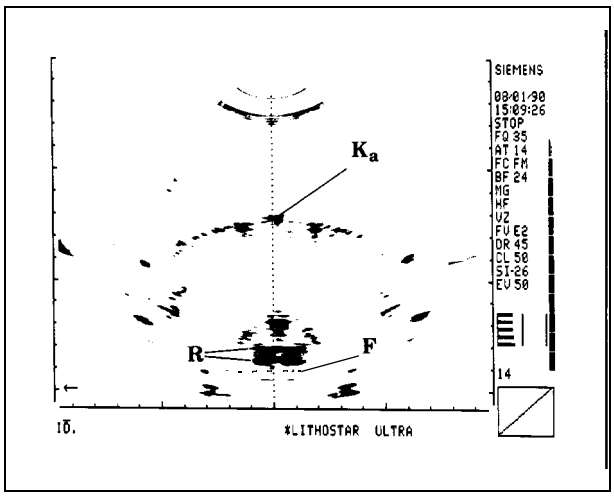


Fig. 2

Adjusting the SONOLINE

- Select the internal ultrasound applicator with the button.
- On the SONOLINE: Set the overall gain control and 5 depth gain control (DGC) slider controls to their middle positions.

Basic Axial and Lateral Settings

- The first time you perform a pressure and position check, preset function keys 3 and 4 of the SONOLINE as described in the section on "Programming the Basic Settings".

Axial Adjustment

- Call up the basic axial setting by entering ° FT I 3 on the SONOLINE keyboard (Fig. 1).
- Optimize the brightness of the ultrasound monitor.
- Adjust the receiving amplifier slider control so that the two horizontal reflections of the sensor electrodes (**R**) can clearly be made out (Fig. 1 and Fig. 2).
- Move shock wave source forward axially toward the coupling location by pressing the button until the horizontal bars of the cross hairs (**F**) appear on the rear horizontal reflection of the sensor electrodes. This compensates for the run time offset caused by the PTU (Fig. 2).

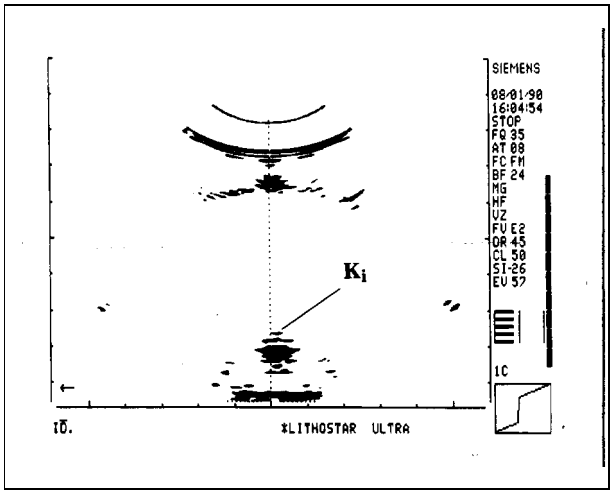


Fig. 3

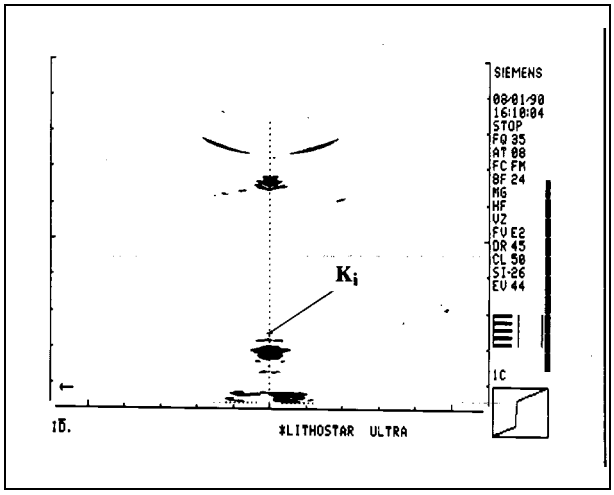


Fig. 4

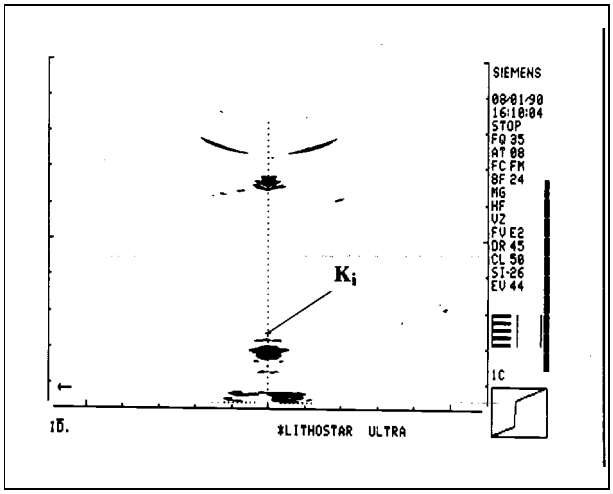


Fig. 5

Sensor Positioning

- Call up the basic lateral setting by entering [° FT] [I] [4] on the SONOLINE keyboard (Fig. 3).
- Use the control knob on the control arm to set the ultrasound probe located inside the shock wave head to its right-hand stop (-90° angle).
- Adjust the overall gain so that the reflection of the inner sensor dome tip ($\mathbf{K_i}$) can be seen as a point.
  If necessary, the sensor dome tip ($\mathbf{K_i}$) can be displayed even better by moving the shock wave source perpendicular to the sectional plane (Fig. 4).
- Move the shock wave source in the sectional plate of the probe until the reflection of the inner sensor dome tip ($\mathbf{K_i}$) lies as close as possible to the median line (Fig. 5).
- Rotate the US probe 90° counter-clockwise (0° angle) until the control knob is positioned vertical.
- Repeat the adjustments shown in Fig. 4 and Fig. 5.

- To check the ultrasound probe, rotate it another 90° counter-clockwise (+90° angle) to determine the position of the dome tip relative to the median line and correct if necessary.

Shock Wave Pressure Check

- Search for focus at energy level 9 (preferably with a scope run time of 145 - 147 µs) (you can make the peak easier detect by steepening the pressure signal when using the scope; this is helpful when searching for the focus). Always wait 5 seconds between shots; no cavitation bubbles should still be visible in the US.
- First search for the peak via fine wobble movements with the US probe in the 0° position.
- Then set the US probe to the 90° position and once again search for the peak with fine wobble movements.
- The focal search must be performed very carefully, since it strongly influences the pressure value.
- In the focal position located, the central axis of the cross hairs should line up with the tip of the sensor dome for both the 0° and the 90° position.
  If this is not the case, the Sonoline must be readjusted.
- The pressure must be determined at energy setting 6 in the focal position located:

  Absolute measurement: 46.5 - 69.3 MPa

  Comparison measurement: Original value ± 12%
- Enter values determined in the certificate.

End of Test

- Remove the Pressure test unit from the shock wave head and deposit it in the SONOLINE cart.
- Unscrew both knurled screws from the shock wave head and screw the holding knob back on.
- Attach the knurled screws to the coupling device for safekeeping.

Programming the Basic Settings

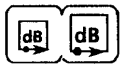
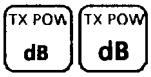
- Programming of the basic settings is required only for the very first pressure check during initial system startup or after replacing the SONOLINE.

Basic Axial Setting [° FT] [I] [3]

- Make the cross hairs visible by pressing the or button.
- Set the ZOOM factor to **AT14** by pressing the or buttons (imaging depth = 14 cm).
- Invert the video image, reduce the monitor brightness if necessary.

Sonoline	Button
SL1	
SI 200 SI 250	or

- Set the transmitting power to SI -16 (transmitting intensity = -16 dB).

Sonoline	Button
SL1	
SI 200 SI 250	or 

- Save the above settings to the SONOLINE by entering the button sequence:

Basic Lateral Setting

- Call up basic axial setting with the button sequence [° FT] [I] [4] .
- Use the or keys to set the ZOOM factor to **AT08** (imaging depth = 8 cm).
- Use the button to select the step function as the brightness function; the curve symbol then appears in the lower right-hand corner of the monitor.

SONOLINE SL 1

- Use the left and right relocate buttons to move the left and right corners of the curve until the curve symbol is identical to the one shown in Fig. 3.

SONOLINE SI 200 / SI 250

- Select the right or left relocate button and shift the left and right corners of the curve with the trackball until the curve symbol is identical to the one shown in Fig. 4.
- Save the above settings to the SONOLINE by entering the button sequence:

System type		
Ser. no. of system		
Customer		
Ser. no. of high voltage charging unit		
Ser. no. of charging power unit		
Ser. no. and type of shock wave generator		
Ser. no. of PTU		
Sensitivity, BNC (absolute measurement)		**mV/MPa**
Sensitivity, LCD (comparison measurement)		**mV/MPa**

Date					
Ser. no. STWK					
Measurement type (**A**bsolute measurement **C**omparison measurement)					
Measurement 1					
Measurement 2					
Measurement 3					
Measurement 4					
Measurement 5					
Mean value					
Pressure value corrected					

Date					
Ser. no. STWK					
Measurement type (**A**bsolute measurement, **C**omparison measurement)					
Measurement 1					
Measurement 2					
Measurement 3					
Measurement 4					
Measurement 5					
Mean value					
Pressure value corrected					

System type		
Ser. no. of system		
Customer		
Ser. no. of high voltage charging unit		
Ser. no. of charging power unit		
Ser. no. and type of shock wave generator		
Ser. no. of PTU		
Sensitivity, BNC (absolute measurement)		**mV/MPa**
Sensitivity, LCD (comparison measurement)		**mV/MPa**

Date					
Ser. no. STWK					
Measurement type (**A**bsolute measurement **C**omparison measurement)					
Measurement 1					
Measurement 2					
Measurement 3					
Measurement 4					
Measurement 5					
Mean value					
Pressure value corrected					

Date					
Ser. no. STWK					
Measurement type (**A**bsolute measurement, **C**omparison measurement)					
Measurement 1					
Measurement 2					
Measurement 3					
Measurement 4					
Measurement 5					
Mean value					
Pressure value corrected					

Changes to previous version 6 - 1

Chap. 0	Front page, Index, Rev.-Status new generated
Chap. 1 - 1	Section: Required Test Equipment Text new added
Chap. 3 - 1	Section: Attaching the Test Unit to the LITHOSTAR Modularis Text new added

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